Regulatory Information Sheet

Product reference:

CC10036743BG FDM BLACK BATHENE PE-1903

It is hereby declared that the above mentioned product is a material that may be lawfully used as a component of plastic articles that will contact food, subject to the restrictions provided below, in compliance with the harmonised legislation in place in the European Union (EU). This product meets the relevant requirements of European Union regulations 1935/2004 and 2023/2006 on materials and articles intended to come into contact with food.

Europe	***Compliant***

The raw materials (polymers, additives or colorants) used in the above mentioned product are compliant with the purity requirements given in Resolution AP(89)1 of Council of Europe or have a suitable listing under COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and its amendments: No 321/2011, No 1282/2011, No 1183/2012, No 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988 and 2019/1338. This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use.

Components with SML	No SML
Dual-use additive (Article 11.3 & Annex IV of EU 10/2011)	None
RESTRICTIONS	Due to carbon black, our product in reference remains in compliance with the European Regulation providing it is used up to 6 % maximum (w/w).

Remark: *The final food contact material or article made from or containing this product as a component, needs to comply with overall and specific migration limit requirements – as specified in various legislations – when tested on the food contact surface with the appropriate food simulants and time/temperature test conditions.*
It is the responsibility of the finished article manufacturer to ensure that all restrictions, and organoleptic requirements, are met by the finished article and that such article is fully compliant with all the relevant EU and member state legislation.

Packaging

No intentional addition of
1. Lead.
2. Mercury.
3. Cadmium.
4. Hexavalent Chromium.

Therefore, compliance with:
• Article 11 of European Parliament and Council **Directive 94/62/EC** of 20 December 1994 on packaging and packaging waste (last amended by Directive 2013/2/EU).
• The requirements of the Model Toxics in Packaging Legislation developed in 1989 by the **CONEG** (Coalition Of NorthEastern Governors) (United States of America)
• Article 4 of the French "**Décret n° 2007-1467 du 12 octobre 2007** " repealing article 4 of the French"Décret n° 98-638 du 20 juillet 1998 relatif à la prise en compte des exigences liées à l'environnement dans la conception et la fabrication des emballages".

Remark: *This, however, does not exclude that trace levels of those substances may be unintentionally present. PolyOne Luxembourg SARL does not check the non detection of those substances.*

Pharmacopoeia

For the following reasons, PolyOne Luxembourg SARL ***cannot declare*** the above-mentioned product to be physiologically safe for the purpose of coloring pharmaceuticals and medical devices:
• There are no general purity requirements for colorants for these applications.
• The specifications in the various monographs of the European Pharmacopoeia on specific substances (e.g. iron oxide, titanium oxide, etc.) are not part of normal quality control.
• Colorants are produced by large-scale industrial processes and not primarily for the medical sector.
• All the regulations relevant to medical applications specify ***testing of the final product*** (Medical Device Directive 93/42/EC, ISO 10993 and/or USP Class VI requirements).

Miscellaneous

No intentional addition of
1. **BADGE:** 2, 2-bis (4-hydroxyphenyl) propane bis (2, 3-epoxypropyl) ether.
2. **BFDGE:** bis (hydroxyphenyl) methane bis (2, 3-epoxypropyl) ethers.
3. **NOGE:** novolac glycidyl ethers.
Or some of their derivatives - Therefore, compliance with **Commission Regulation 1895/2005/EC** of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (this Regulation repeals Directive 2002/16/EC & 2004/13/EC).

No intentional addition of **Azodyes** which, by reductive cleavage of one or more azo groups, may release one or more of the aromatic amine listed in the appendix of 2002/61/EC. Therefore, compliance with Directive 2002/61/EC of the European Parliament and of the Council of 19 July 2002 amending for the nineteenth time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (Azocolourants).

No intentional addition of **Bisphenol A** (CAS Reg. Nr: 80-05-7 - 25068-38-6)

Remark: *This, however, does not exclude that trace levels of those substances may be unintentionally present. PolyOne Luxembourg SARL does not check the non detection of those substances.*

Comment

It remains valid 12 months after the date issue or until changes of the cited regulations become effective.

It applies to the masterbatch manufactured in Europe and remains valid 12 months after the date of issue or until changes of the cited regulations become effective.

This declaration applies only to the raw materials used in the manufacture of the product mentioned, and may not be extended to end products obtained by:

• Any ulterior modification due to the addition of any other substances not in conformity with the related regulations,
• An improper use of the masterbatch or end product,
• Any processing technique or conditions of use which could lead to the masterbach deterioration.

This declaration does not waive the responsibility of the user who must check whether the end products are appropriate for the specific intended use.

It is our understanding that the above-mentioned product is used in an unaltered form and within the appropriate plastic molding conditions.

Date : **3/11/2020**

For the Supplier,

Neéma Perramant
European Regulatory Specialist

PolyOne Luxembourg SARL
European Regional Headquarters
Route de Bastogne 19
Pommerloch, Luxembourg L-9638

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